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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,882	07/19/2006	Lutz F. Schweiger	088736-0113	9918

22428 7590 12/10/2009
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

MCDOWELL, BRIAN E

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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12/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,882	Applicant(s) SCHWEIGER ET AL.	
	Examiner BRIAN MCDOWELL	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 69-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 69-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/22/2009, 9/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

/BEM/

DETAILED ACTION***Status of Claims***

Claims 1 and 69-114 are pending in the instant application.

Status of Rejections***35 USC § 112 (2nd Paragraph)***

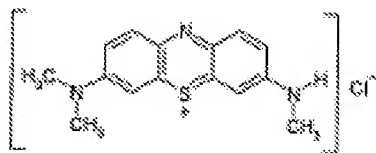
Applicant's amendment of the claims, see Remarks, filed 9/30/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 3/23/2009, has been fully considered and the rejection has been overcome.

35 USC § 103

The 103 rejection of currently pending claims 1 and 69-114 is still maintained for the reasons stated previously of record and herein.

Applicant's arguments, see Remarks, filed 9/30/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 3/23/2009, have been fully considered but are not found persuasive.

Applicant's arguments stem from the fact that the cited references fail to teach every element of the claimed invention. The examiner respectfully disagrees. As applicant had mentioned, the instant claims are drawn to a method of [¹¹C]-radiolabelling the following phenothiazine compound:



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with [^{11}C]methyl trifluoromethanesulfonate, also known as [^{11}C]methyl triflate, under standard basic conditions. The compound may be used for PET imaging and treating skin cancer such as melanoma.

Applicant adamantly insisted that Nagren only taught ^{11}C -radiolabelling of amides and thiols. However, this is not the case since Nagren explicitly suggested that the preparation of PET radioligands by *N*-methylation of amines may be accomplished using mild conditions (e.g., methylation of the free base using a mild base, see page 837, third paragraph). Furthermore, as applicant had pointed out, Nagren suggested that [^{11}C]methyl triflate provided faster reaction times and lower reaction temperatures when compared with [^{11}C]-methyl iodide. Thus, one of ordinary skill would have been motivated to employ [^{11}C]methyl triflate in the claimed method. The claims are drawn to a method of radiolabelling a compound, not comparisons of isotopic half-lives between carbon and iodine.

As stated previously, Link taught that radioderivatives of methylene blue (compound shown above) may be used for both diagnosis and therapy of melanoma (see abstract of document).

Therefore, one of ordinary skill would have been motivated and have a reasonable expectation of successfully radiolabelling methylene blue with [^{11}C]methyl trifluoromethanesulfonate under basic conditions. Claims citing reaction conditions and purification methods are considered routine practices in the field of synthetic chemistry and would fall under routine experimentation.

“Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

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experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955)

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN MCDOWELL/
Patent Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, AU 1624